

REMARKS

Claims 1, 3, 4, 7-38, 40, 41, 44-80, 82, and 84-94 are pending. Claims 38, 40, 41, 44-80, and 82 are withdrawn as being directed to a non-elected invention. Claims 1, 3, 4, 7-37, and 84-94 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description (new matter). By this reply, Applicants amend the specification, request rejoinder of claims 38, 40, 41, 44-80, and 82, and address each of the Examiner's rejections.

Telephone Interview with the Examiner

Applicants wish to thank Examiner Azpuru for the courtesy of a telephonic interview on January 13, 2009, during which the present rejection was discussed.

Information Disclosure Statement

Applicants note that the Form PTO-1449s that were filed with Information Disclosure Statements on May 8, 2007, and May 21, 2007, have not been initialed and returned. Applicants respectfully request that the Examiner initial and return the Form PTO-1449s with the next Office Action.

Support for the Amendment

Support for the amendment to the specification is found in original claims 2-10, 18-22, and 36. No new matter is added by the amendment.

Rejoinder

Claims 38, 40, 41, 44-80, and 82 are withdrawn from consideration. In response to the Restriction Requirement mailed on October 16, 2007, Applicants were required to choose between four invention groups. Applicants elected the claims of Group I directed to an osteoinductive powder. Applicants have amended withdrawn claims 38, 40, 41, 44-80, and 82 during prosecution to include the same limitations as examined claims 1, 3, 4, 7-37, and 84-94. Thus, upon the allowance of claims 1, 3, 4, 7-37, and 84-94, Applicants respectfully request reconsideration of the restriction requirement and rejoinder and allowance of withdrawn claims 38, 40, 41, 44-80, and 82 (see M.P.E.P. § 821.04).

Rejections under 35 U.S.C. § 112, first paragraph

The Office rejects claims 3, 4, 7-10, 15, 18-22, 33, and 36 under 35 U.S.C. § 112, first paragraph, for new matter, stating that “applicant should amend the specification to reflect the same values set out in the claims in order to make the specification and claims commensurate. Doing so will remove the rejection under 35 U.S.C. 112, first paragraph for written description” (Office Action, p. 2). As suggested by the Office, Applicants have amended the specification to include the subject matter of original claims 2-10 and 18-22. Applicants note that the subject matter of present claims 33 and 15 is found in the present specification at, e.g., page 6, lines 16-19, and page 13, lines 9-12, respectively. Applicants respectfully request that this rejection be withdrawn.

The Office also rejects claims 1, 3, 4, 7-37, and 84-94 under 35 U.S.C. § 112, first paragraph, for new matter, stating that “Applicant has amended the claims to include

concentration ranges which are not specifically set out in the originally filed specification. As such, they are considered new matter” (Office Action, p. 3). Applicants respectfully traverse this rejection.

As was discussed in the Reply to Office Action filed on October 20, 2008, support for the amendment to claims 1, 37, 38, 77, 78, and 80 is found in the specification at, e.g., Table 2, pages 44-45, and page 11, lines 16-21. Table 2 is reproduced below for the Office’s review.

TABLE 2

Bone Induction Scores for Selected DBM – Calcium Phosphate Formulations					
Amount DBM³	DBM Type, Size (µm)	Amount Cohesiveness Agent	Cohesiveness Agent Type	Amount Calcium Phosphate Powder	Bone Inductivity Score (0-4)
30	Particles, 125-850	15	CMC ⁴ Powder	55	0.6
50	Particles, 125-850	15	CMC Powder	35	0.8
40	Fibers, 250-2mm	0	-	60	0.8
50	Particles, 53-125	5	CMC Powder	45	1.0
50	Particles, 125-850	5	CMC Powder	45	1.6
50	Particles, 500-850	5	CMC Powder	45	1.8
50	Particles, 125-850	0	-	50	1.0
50	Particles, 125-850	5	CMC Powder	45	1.0
60	CMC Coated Particles, 125-850	0	-	40	1.0
60	CMC Coated Particles, 125-850	10	CMC Powder	30	1.0
40	Fibers, 250-2mm	5	CMC Powder	55	1.3
70	Particles, 125-850	5	CMC Powder	25	2.0
60	Particles, 125-850	10	PVP ⁵	30	2.0
60	Particles, 53-125	10	CMC Powder	30	3.0
60	Particles, 125-850	10	CMC Powder	30	2.0
GRAFTON® DBM Putty					2.7
GRAFTON® DBM Flex					0.8
GRAFTON® DBM Matrix					0.5
Osteofil®					0.8

³ Amounts of DBM, Binder, and Calcium Phosphate Powder are provided as weight percentages of the powder component of the implant material.

⁴ CMC denotes carboxymethylcellulose.

⁵ PVP denotes polyvinylpyrrolidone.

Table 2 clearly shows formulations for several compositions in which DBM is present in the compositions within a range from about 40 wt% to about 70 wt% (column 1). Table 2 also shows that these compositions include a calcium phosphate powder in an amount in the range of about 25 wt% to about 60 wt% (column 5). Table 2 provides considerable written description support for the concentration ranges recited in present claims 1, 3, 4, 7-37, and 84-94. *See, e.g., Ex parte Noelle*, Appeal No. 2008-0011 (Bd. Pat. App. & Inter. 2008) (reversing the Office's written description rejection of claim 7 and finding written description support for the range of 6 to 10 days from a specification that disclosed "about 1-2 days to 30 days, more typically about 5-15 days, and most typically about 10 days"); *Ex parte van Beek*, Appeal No. 2006-0151 (Bd. Pat. App. & Inter. 2006) (reversing the Office's written description rejection of claims 1-7 and 10-13 and finding written description support for the open-ended phrase "at least 5% by weight" based on the specification's generic disclosure coupled with the specification's specific examples of compositions having at least 5% by weight of lysophospholipids); *Ex parte Belardelli*, Appeal No. 2008-1869 (Bd. Pat. App. & Inter. 2008) (reversing the Office's written description rejection of claims having the limitation of specific growth factors at a concentration in a range of 500-1,000 IU/ml based on support in the specification of multiple overlapping concentration ranges).


Applicants respectfully request that the rejection of claims 1, 3, 4, 7-37, and 84-94 under 35 U.S.C. § 112, first paragraph, for new matter, be withdrawn.

CONCLUSION

In view of the above remarks, Applicants respectfully submit that the present claims are in condition for allowance, and such action is respectfully requested.

If there are any additional charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul T. Clark", written over a horizontal line.

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